EXHIBIT 15

All disputed RFAs in numerical order

RFAs 1-2, 4-18, 20-24, 26-29, 31, 34, 39, 41-42, 45, 47, 49, 51, 53-57, 60-67, 69-72, 74-92, 94-95, 101, 107-108, 110, 113-125, 127, 130-140

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No. 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: Suits Naming Saint Thomas Outpatient Neurosurgical Center, LLC And Related Defendants	

PLAINTIFFS' STEERING COMMITTEE'S RESPONSES TO SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION, JOHN W. CULCLASURE, MD, AND DEBRA V. SCHAMBERG, RN CNOR'S, FIRST REQUESTS FOR ADMISSIONS PROPOUNDED TO THE PLAINTIFFS

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure, the Plaintiffs' Counsel hereby responds to the First Interrogatories and Requests for Admission Propounded by the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Clinic"), Howell Allen Clinic, John W. Culclasure, MD, and Debra V. Schamberg, RN (collectively "Defendants" or "Saint Thomas Clinic Defendants").

INSTRUCTIONS DEFINITIONS AND OBJECTIONS

1. The term "Plaintiffs" shall mean all Plaintiffs who have pending cases against any of the Saint Thomas Clinic Defendants in active cases in the MDL.

2. The term "Plaintiffs' Counsel" shall mean the Tennessee State Chair as designated by Plaintiffs' Steering Committee pursuant to MDL Order No. 2.

REQUEST FOR ADMISSION NO. 1:

The Health Care Procedure Coding System ("HCPCS") code, J1040, existed in 2012 for billing third-party payors and/or patients separately for the steroid administered during epidural steroid injections.

RESPONSE TO REQUEST FOR ADMISSION NO. 1:

Admitted that HSPCS code J1040 existed in 2012 for billing purposes and for providing additional detail about a procedure. Denied to the extent that the RFA implies that the use of such code would indicate and/or lead to a separate payment for the steroid administered during epidural steroid injections.

REQUEST FOR ADMISSION NO. 2:

No other HCPCS code existed to bill third-party payors and/or patients separately for the steroid administered during epidural steroid injections.

RESPONSE TO REQUEST FOR ADMISSION NO. 2:

Denied.

REQUEST FOR ADMISSION NO. 4:

NECC and its owners, managers, employees, and agents owed a duty to the Plaintiffs to comply with the recognized standard of acceptable professional practice for compounding or manufacturing MPA and/or to exercise reasonable care when compounding or manufacturing the MPA at issue.

RESPONSE TO REQUEST FOR ADMISSION NO. 4:

. Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 5:

NECC and its owners, managers, employees, and agents breached their duty to the Plaintiffs.

RESPONSE TO REQUEST FOR ADMISSION NO. 5:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 6:

The breach of duty the owed by NECC and its owners, managers, employees and agents to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 6:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 7:

Medical Sales Management, Inc. and/or Medical Sales Management SW, Inc. and their owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when marketing and selling NECC's products, including MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 7:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 8:

Medical Sales Management, Inc. and/or Medical Sales Management SW, Inc., and their owners, managers, employees, and agents, breached their duty to the Plaintiffs when marketing and selling NECC's products.

RESPONSE TO REQUEST FOR ADMISSION NO. 8:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 9:

Medical Sales Management, Inc. and/or Medical Sales Management SW, Inc. and their owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 9:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin*

Servs., Inc., Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 10:

When constructing the cleanroom(s) used to compound the MPA at issue, Liberty Industries, Inc. and its owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when constructing the cleanroom(s).

RESPONSE TO REQUEST FOR ADMISSION NO. 10:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 11:

When constructing the cleanroom(s) used to compound the MPA at issue, Liberty Industries, Inc. and its owners, managers, employees, and agents, breached their duty to the Plaintiffs.

RESPONSE TO REQUEST FOR ADMISSION NO. 11:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 12:

Liberty Industries, Inc. and its owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 12:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 13:

UniFirst Corporation d/b/a UniClean Cleanroom Services and its owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when servicing NECC's cleanroom(s) used to compound the MPA at issue.

RESPONSE TO REQUEST FOR ADMISSION NO. 13:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 14:

UniFirst Corporation d/b/a UniClean Cleanroom Services and its owners, managers, employees, and agents breached their duty to the Plaintiffs when servicing NECC's cleanroom(s) used to compound the MPA at issue.

RESPONSE TO REQUEST FOR ADMISSION NO. 14:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 15:

UniFirst Corporation d/b/a UniClean Cleanroom Services and its owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 15:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 16:

ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories and its owners, managers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care when conducting sterility testing on MPA from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 16:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin*

Servs., Inc., Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 17:

ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories and its owners, managers, employees, and agents breached their duty to the Plaintiffs when conducting sterility testing on MPA produced by NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 17:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 18:

ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories and its owners, managers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 18:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 20:

The recognized standard of acceptable professional practice did not require a potential customer of NECC to submit a federal Freedom of Information Act or Massachusetts Public Records Act request for information regarding NECC prior to purchasing.

RESPONSE TO REQUEST FOR ADMISSION NO. 20:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 21:

The median response time by the FDA to federal Freedom of Information Act requests in calendar year 2011 was between 21 and 40 days for "simple" requests, and between 181 and 200 days for "complex" requests.[1]

RESPONSE TO REQUEST FOR ADMISSION NO. 21:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is sufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 22:

The FDA's median response time to federal Freedom of Information Act requests in 2012 was between 141 and 160 days for "simple" requests and between 201 and 300 days for "complex" requests.[2]

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[1] Exhibit A includes four charts from http://www.foia.gov/data.html which generates reports on response time to federal Freedom of Information Act requests. The data is sorted by response time for each agency and fiscal year. The four charts in Exhibit A were generated on the website by narrowing the terms to FDA data for "simple" and "complex" request response time for 2011 and 2012, respectively. Median response time is readily apparent from the chart data.

RESPONSE TO REQUEST FOR ADMISSION NO. 22:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 23:

The FDA's admitted duty is to be "responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."[3]

RESPONSE TO REQUEST FOR ADMISSION NO. 23:

Admitted that the link provided by Defendants in the footnote to Request for Admission 23 states that the FDA is "responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our

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[2] Exhibit A includes four charts from http://www.foia.gov/data.html which generates reports on response time to federal Freedom of Information Act requests. The data is sorted by response time for each agency and fiscal year. The four charts in Exhibit A were generated on the website by narrowing the terms to FDA data for "simple" and "complex" request response time for 2011 and 2012, respectively. Median response time is readily apparent from the chart data.

[3] *See* the FDA's website at: http://www.fda.gov/aboutfda/whatwedo/default.htm.

nation's food supply, cosmetics, and products that emit radiation." To the extent that the Request for Admission is meant to require the Plaintiffs' Counsel to admit that the aforementioned quote establishes a legal duty upon the FDA, denied. Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 24:

On August 6, 2009, during a speech at the Food and Drug Institute, FDA Commissioner Margaret Hamburg stated:

> When the FDA finds that a firm is significantly out of compliance, we expect a prompt response to our findings. Once the FDA provides inspection findings identifying a serious problem, the firm will generally have no more than fifteen working days in which to respond before the FDA moves ahead with a warning letter or enforcement action. This will help FDA issue warning letters on a timely basis and facilitate prompt corrective action. . . . [T]he FDA will take responsible steps to speed the issuance of warning letters. . . . The FDA is fortunate to have received significant funding increases for the current and next fiscal year that will be devoted to additional inspection and compliance activities that will support the elements of an effective enforcement strategy that I have outlined.[4]

RESPONSE TO REQUEST FOR ADMISSION NO. 24:

Admit that the linked document contains the quotation contained in RFA 24. Plaintiffs object to this RFA to the extent that it seeks to establish that the quotation establishes a legal

[4] http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm; http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-report-fdas-contribution-to-the-drug-shortage-crisis.pdf.

duty or breach of that duty on behalf of the FDA because any such RFA would require Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 26:

The FDA and its officers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care in regulating NECC, and deciding whether to permit NECC to continue to compound and manufacture medication despite repeated complaints and inspections in the years leading up to 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 26:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 27:

The FDA and its officers, employees, and agents breached their duty to the Plaintiffs in regulating NECC and deciding to allow NECC to continue to compound medication despite repeated complaints and inspections in the years leading up to 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 27:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 28:

The FDA and its officers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 28:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 29:

Prior to September 18, 2012, NECC violated the FDA Compliance Policy Guidance on Compounding[5] in the following ways:

a. NECC failed to operate in conformance with applicable state law regulating the practice of pharmacy.

b. NECC compounded drug products that were commercially available in the marketplace or that were essentially copies of commercially-available, FDA-approved drug products.

c. NECC used commercial-scale manufacturing or testing equipment when compounding drug products.

RESPONSE TO REQUEST FOR ADMISSION NO. 29:

Plaintiffs object to this RFA because the Request does not identify any specific provisions of the compliance policy which are alleged to be violated. Plaintiffs further object to this RFA because it is vague and unduly burdensome in that the Request is unlimited time and taken literally would require Plaintiffs to investigate events occurring as early as the foundation of NECC. Plaintiffs further object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

[5] A copy of the Compliance Policy Guidance on Compounding in effect until December 2013 is attached as Exhibit B.

REQUEST FOR ADMISSION NO. 31:

Prior to September 18, 2012, the FDA had the authority to inspect, regulate, and, if need be, shut down NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 31:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 34:

From September 2012 to October 2013, Congress did not pass any laws altering or expanding the FDA's authority to regulate or inspect compounding pharmacies.

RESPONSE TO REQUEST FOR ADMISSION NO. 34:

Plaintiffs object to this RFA because it is unduly burdensome in that it would require the Plaintiffs to review every bill passed by Congress during the time period to determine whether

[7] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperations andPolicy/ORA/ORAElectronicReadinpRoom/ucm340853.htm.

they directly or indirectly altered or expanded the FDA's authority to regulate or inspect compounding pharmacies. This RFA further seeks information that is not reasonably calculated to lead to the discovery of admissible evidence and is vague.

REQUEST FOR ADMISSION NO. 39:

Exhibit C is a majority staff report drafted by the Committee on Energy and Commerce of the U.S. House of Representatives for the 113th Congress entitled "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"

RESPONSE TO REQUEST FOR ADMISSION NO. 39:

Denied as phrased as the Request as posed mischaracterized the nature of Exhibit C.

REQUEST FOR ADMISSION NO. 41:

The presentations, emails, letters, press announcements, memoranda, drafts, and inspection requests created by governmental employees, including employees of the FDA,

during the ongoing investigation of NECC, cited within Exhibit C, are all records or statements of a public office as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 41:

Denied.

REQUEST FOR ADMISSION NO. 42:

Before September 18, 2012, a search for information regarding NECC on the FDA website would have identified the FDA's 2006 Warning Letter as the only regulatory action by the FDA against NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 42:

Plaintiffs object to this Request because it is vague in that it is unlimited time and cannot admit or deny based on the timeframe covered by this RFA. Plaintiffs further object to this Request to the extent that it requires the Plaintiffs to recreate a search that could have been done over two years ago. Plaintiff further objects to this Request because it would require, even if possible, Plaintiffs' Counsel to conduct a search for every day from the time the FDA created its website through September 18, 2012

Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in

order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 45:

The FDA did not issue a Public Health Alert (or any other specific alert) to health care providers, warning them of the problems at NECC that the FDA identified in the Warning Letter, on December 4, 2006, or on any subsequent date, prior to September 18, 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 45:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 47:

Prior to September 18, 2012, the FDA did not take action against NECC after sending the December 4, 2006, Warning Letter, even though the Warning Letter threatened "additional regulatory action without further notice."

RESPONSE TO REQUEST FOR ADMISSION NO. 47:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 49:

The FDA did not inspect or take action against NECC in response to the adverse event report in Request for Admission 48, despite the FDA's 2006 Warning Letter to NECC stating, "We are especially concerned with the potential microbial contamination associated with splitting Avastin — a single-use, preservative-free, vial — into multiple doses. When used intravitreaily [sic] microbes could cause endophtalmitis [sic] which has a high probability for significant vision loss."[23]

RESPONSE TO REQUEST FOR ADMISSION NO. 49:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to

[22] *See* Exhibit C.
[23] *See* Exhibit C.

respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 51:

The FDA Center for Drug Evaluation and Research ("CDER") decided to inspect NECC as a result of the betamethasone reports and a separate report regarding mesotherapy products.[25]

RESPONSE TO REQUEST FOR ADMISSION NO. 51:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities). Plaintiffs further object to this Request to the

[24] *See* Exhibit C.
[25] *See* Exhibit C.

extent that it requires Plaintiffs' Counsel to speculate as to why the FDA decided to take action and fails to identify any time frame when any such decision was or was not made. Any such Request is beyond the requirements of Rule 36.

[26] *See* Exhibit C.
[27] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 53:

The FDA intended to seek an injunction against NECC if it was still compounding when the inspection referred to in Request for Admission 52 occurred.[27]

RESPONSE TO REQUEST FOR ADMISSION NO. 53:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to

[26] *See* Exhibit C.
[27] *See* Exhibit C.

respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 54:

CDER's Division of Manufacturing and Product Quality planned to assist with manufacturing and sterility assurance issues during the inspection referred to in Request for Admission 52.[28]

RESPONSE TO REQUEST FOR ADMISSION NO. 54:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 55:

On October 9, 2008, while discussions within the FDA regarding inspecting NECC were ongoing, the Los Angeles District Office of the FDA received a complaint about a patient

[28] *See* Exhibit C.

requiring hospitalization after receiving phosphatidylcholine, a mesotherapy product, from NECC.[29]

RESPONSE TO REQUEST FOR ADMISSION NO. 55:

Admit that the Los Angeles District Office received a complaint on October 9, 2008 about a patient requiring hospitalization after receiving phosphatidylcholine from NECC. As to the admission or denial of any other statement contained in RFA 55, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 56:

According to the report referenced in Request for Admission 55, after the initial infusion period, the patient "developed [a] burning sensation" and a "swollen arm and hand." After the patient was discharged, he could not swallow food or liquid, vomited, and urinated blood. He

[29] *See* Exhibit C.

was "admitted to an emergency room three more times," and "[t]he physician found blood clots in his arm and hand."[30]

RESPONSE TO REQUEST FOR ADMISSION NO. 56:

Admitted that Exhibit C contains the above-quotations. To the extent that this RFA requests that the Plaintiffs' Counsel admit or deny that these events actually took place, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 57:

The FDA's New England District Office was informed of the facts described in Requests for Admissions 55-56 on October 16, 2008, and planned to "make sure the investigator follow[ed] up" on the report during the planned inspection of NECC.[31]

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[30] *See* Exhibit C.
[31] *See* Exhibit C.

RESPONSE TO REQUEST FOR ADMISSION NO. 57:

Plaintiffs object to this RFA as it is vague in that it is unclear in that the Request does not set forth simply and directly the matters which are to be admitted or denied. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[32] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 60:

The FDA did not perform the follow-up inspection promised in its letter of October 31, 2008, and never returned to inspect NECC until after September 18, 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 60:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 61:

In 2009, the FDA received testing results for the phosphatidylcholine referenced in Requests for Admissions 55-57, confirming the medication was super-potent and displayed signs of degradation.[33]

RESPONSE TO REQUEST FOR ADMISSION NO. 61:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by Plaintiffs' Counsel is insufficient to enable Plaintiffs' Counsel to admit or deny this request as the document referenced in the Exhibit cannot be located. Therefore, the information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 62:

On February 11, 2009, after receiving the testing results described in Request for Admission 61, a New England District compliance officer emailed a number of his colleagues, stating "ODER wants us to immediately (today) go [to] NECC to determine if the firm is willing to recall the Phosphatidyl choline [sic] injection it compounds. The drug is superpotent and not

[33] *See* Exhibit C.

approved and should be recalled. We want to determine the batch size, and where distributed. The recall part should be done immediately and can be separate from the inspection."[34]

RESPONSE TO REQUEST FOR ADMISSION NO. 62:

Admitted that the quoted email appears in the cited Exhibit C. To the extent that the RFA requires Plaintiffs' Counsel to admit or deny whether the events cited in the report ever took place, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 63:

The recall referred to in Request for Admission 62 did not happen the following day, and, as of February 17, 2009, the FDA had not even informed NECC of the testing results.[35]

RESPONSE TO REQUEST FOR ADMISSION NO. 63:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to

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[34] *See* Exhibit C.
[35] *See* Exhibit C.

enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 64:

The planned inspection of NECC, which was rescheduled to take place "around March 23, 2009," was postponed for a second time on March 18, 2009, to allow the FDA to broaden the scope of the inspection assignment to establish that NECC was acting as a manufacturer rather than a traditional compounding pharmacy, in anticipation of the FDA having to defend enforcement actions taken against NECC in court, such as the seizure of products or an injunction.[36]

RESPONSE TO REQUEST FOR ADMISSION NO. 64:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain

[36] *See* Exhibit C.

documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 65:

Near the end of 2009, the FDA received complaints about NECC's solicitation and distribution of erythromycin without patient-specific prescriptions and NECC's sale of sodium tetradecyl sulfate to a physician in North Carolina for use in treating varicose veins, when there was only one commercially-available product indicated for such treatment.[37]

RESPONSE TO REQUEST FOR ADMISSION NO. 65:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[37] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 66:

According to the complaint report, the FDA was aware that NECC was compounding sodium tetradecyl sulfate and stated that it would be issuing an inspection assignment for NECC "in the future."[38]

RESPONSE TO REQUEST FOR ADMISSION NO. 66:

Denied as phrased as the aforementioned complaint report does not state that the FDA would be issuing an "inspection assignment" for NECC.

REQUEST FOR ADMISSION NO. 67:

In September 2010, the FDA received a report that NECC was soliciting sales of an antibiotic during a shortage, along with a number of other products.[39]

RESPONSE TO REQUEST FOR ADMISSION NO. 67:

Admit that the FDA received a report in September 2010 that NECC was soliciting sales of an antibiotic during a shortage. Denied as to whether sales were also solicited for a "number of other products."

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[38] *See* Exhibit C.
[39] *See* Exhibit C.
[40] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 69:

As early as May 11, 2011, the FDA had "determined that NECC was a manufacturer, not a compounding pharmacy."[41]

RESPONSE TO REQUEST FOR ADMISSION NO. 69:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 70:

Less than two weeks later, on May 24, 2011, the Mass. BoP inspected NECC's facility after NECC updated its facility and moved into adjacent space, and the Mass. BoP allowed NECC to continue to compound medications.

[41] *See* Exhibit C.

RESPONSE TO REQUEST FOR ADMISSION NO. 70:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 71:

On July 16, 2012, the Denver District Office of the FDA again contacted the New England District Office to report that NECC had violated the Colorado Board of Pharmacy's cease and desist order.[42]

RESPONSE TO REQUEST FOR ADMISSION NO. 71:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain

[42] *See* Exhibit C.

documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 72:

Prior to September 18, 2012, the FDA took no action against NECC in response to the Denver District Office's report.[43]

RESPONSE TO REQUEST FOR ADMISSION NO. 72:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[43] *See* Exhibit C.

REQUEST FOR ADMISSION NO. 74:

Prior to September 18, 2012, the FDA had the authority to inspect Analytical Research Laboratories to ensure it was engaged in safe, proper testing of medications.

RESPONSE TO REQUEST FOR ADMISSION NO. 74:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 75:

The publicly-stated mission of the Mass. BoP is:

> To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Massachusetts through the regulation of the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in the public interest. The Massachusetts Board of Registration In Pharmacy will assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and openness.[44]

RESPONSE TO REQUEST FOR ADMISSION NO. 75:

Plaintiffs' Counsel attempted to access the link provided in Request for Admission No. 75 but was unable to do so. As a result, Plaintiffs' Counsel cannot admit or deny the Request for Admission as posed. Moreover, to the extent the RFA is meant to establish the Mass. Board of Pharmacy's duty to Plaintiffs in this case, Plaintiffs object to this Request because it requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 76:

The Mass. BoP and its officers, employees, and agents owed a duty to the Plaintiffs to exercise reasonable care in regulating NECC and deciding whether to allow NECC to continue to compound medication despite repeated complaints and inspections before May of 2012.

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[44] *See* the Massachusetts Board of Registration in Pharmacy website at: http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/about/about-the-board.html.

RESPONSE TO REQUEST FOR ADMISSION NO. 76:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 77:

The Mass. BoP and its officers, employees, and agents breached their duty to the Plaintiffs in regulating NECC and deciding to continue to permit NECC to compound medication despite repeated complaints and inspections in the years leading up to 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 77:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 78:

The Mass. BoP and its officers, employees, and agents' breach of their duty to the Plaintiffs was a proximate cause of the Plaintiffs' alleged injuries and damages.

RESPONSE TO REQUEST FOR ADMISSION NO. 78:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin*

Servs., Inc., Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 79:

Prior to September 18, 2012, the Mass. BoP had the authority to inspect, regulate, and, if need be, summarily close NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 79:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

Plaintiffs further object in that the term "summarily close" is vague.

REQUEST FOR ADMISSION NO. 80:

Prior to September 18, 2012, a search on the Mass. BoP website for regulatory actions against NECC, Barry Cadden, Lisa Cadden, and/or Glenn Chin would have revealed no disciplinary actions.[45]

RESPONSE TO REQUEST FOR ADMISSION NO. 80:

Plaintiffs object to this Request to the extent that it requires the Plaintiffs to recreate a search that could have been done over two years ago. Plaintiffs further state that taken literally, this Request requires Plaintiffs' Counsel to search, even if possible, the relevant website for

[45] *See* Office of Edward Markey, Compounding Pharmacies, Compounding Risk at pp. 3-4 (Oct. 29, 2012), *available at* http://www.snmmi.org/files/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL_0_1382017898361_1.pdf (last visited Oct. 8, 2014).

every day that it existed prior to September 18, 2012. Any such Request is unduly burdensome. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 81:

In 1999, after receiving a report that NECC had violated Mass. BoP regulations by providing blank prescription pads in its solicitations to doctors, the Mass. BoP initiated an investigation, but allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 81:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents

within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 82:

In 2001, after receiving a report from the Idaho Board of Pharmacy that NECC was soliciting business for drug products which should have been discontinued by the manufacturer, the Mass. BoP initiated an investigation of NECC, but allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 82:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v.*

Champlain Enterprises, Inc., 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 83:

In 2002, after receiving a report from the Nevada Board of Pharmacy that NECC was selling products to physicians in Nevada which were not approved by the FDA, the Massachusetts Board of Pharmacy initiated an investigation of NECC, but allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 83:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 84:

Between 2002 and 2004, the Mass. BoP received complaints from the boards of pharmacy for the states of Texas, South Dakota, Iowa, and Wisconsin reporting that NECC was illegally soliciting out-of-state prescriptions for office use, but the Mass. BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 84:

Plaintiffs object to this RFA as it is overly broad and unduly burdensome in that it requires Plaintiffs to review all communications from the referenced boards of pharmacy to the Massachusetts Board of Pharmacy during the relevant time period. Plaintiffs state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Further, to the extent that this RFA is meant to reference documents referenced in Exhibit C, those documents do not come from the "boards of pharmacy" from the states identified, but rather come from individual pharmacists. Therefore, to the extent that this is meant to reference those complaints, this RFA is denied.

REQUEST FOR ADMISSION NO. 85:

On February 5, 2003, the FDA and Mass BoP held a joint meeting to review NECC's inspection history and to formulate a joint state-federal strategy regarding NECC; the participants decided that the Mass. BoP would be primarily responsible for achieving safe compounding practices at NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 85:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 86:

On April 27, 2004, the FDA and Mass BoP conducted a joint inspection of NECC after receiving two (2) new complaints against NECC. The FDA and Mass BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 86:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 87:

On September 23, 2004, the FDA and Mass BoP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use. The FDA and Mass BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 87:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made

reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 88:

In calendar year 2006, Pharmacy Support, Inc. conducted two (2) independent audits of NECC, both identifying multiple problems at NECC, but the Mass. BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 88:

Plaintiffs object to this RFA to the extent that it fails to identify the relevant report to which it was referencing. Plaintiffs' Counsel is not in possession of the referenced report and without such reference cannot admit or deny the request as posed. Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36

does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 89:

In July 2011, the Mass. BoP was notified that NECC had violated a cease and desist order issued by the Colorado Board of Pharmacy; the Mass. BoP allowed NECC to continue to compound medication.

RESPONSE TO REQUEST FOR ADMISSION NO. 89:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 90:

Prior to September 18, 2012, the DEA had the authority to inspect, regulate, and, if need be, revoke NECC's "practitioner" registration.

RESPONSE TO REQUEST FOR ADMISSION NO. 90:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 91:

Prior to September 18, 2012, the Tennessee Board of Pharmacy had the authority to inspect, regulate, and, if need be, revoke NECC's Tennessee license.

RESPONSE TO REQUEST FOR ADMISSION NO. 91:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 92:

Prior to September 18, 2012, every state that issued a license to NECC had the authority to inspect, regulate, and, if need be, publicly revoke NECC's license.

RESPONSE TO REQUEST FOR ADMISSION NO. 92:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 94:

The FDA issued the corresponding number of Warning Letters in each of the years reflected in the columns below

a) 1998 — 814

b) 1999 — 979

c) 2000 — 1,188

d) 2001 — 1,366

e) 2002 — 724

f) 2003 — 676

g) 2004 — 716

h) 2005 — 508

i) 2006 — 468

[46] Review recorded statement attached as Exhibit D.

j) 2007 — 376

k) 2008 — 438

l) 2009 — 572

m) 2010 — 619

n) 2011 — 746

o) 2012 — 733.[47]

RESPONSE TO REQUEST FOR ADMISSION NO. 94:

Plaintiffs object to this Request because it seeks information that is not reasonably calculated to lead to the discovery of admissible evidence is overly broad, unduly burdensome, and not otherwise discoverable under Rule 26. To the extent that a response is required, the RFA is denied because the referenced document does not contain the information referenced in RFA 94.

REQUEST FOR ADMISSION NO. 95:

Teva Pharmaceuticals USA, Inc. ("Teva") is an FDA-registered manufacturer that manufactured MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 95:

Admit that an entity listed as "Teva Pharmaceuticals USA, Inc. is listed on the FDA's "Drug Establishments Current Registration Site." After making reasonable inquiry, Plaintiffs' Counsel is without sufficient information to admit or deny any other statement in this Request.

[47] *See* the DHH website at: http://www.hhs.gov/budget/fy2014/fy-2014-budget-in-brief.pdf.

REQUEST FOR ADMISSION NO. 101:

Sandoz, Inc. ("Sandoz") is an FDA-registered manufacturer that manufactured MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 101:

Admitted that an entity listed as "Sandoz, Inc." is listed on the FDA's "Drug Establishments Current Registration Site." After making reasonable inquiry, Plaintiffs' Counsel is without sufficient information to admit or deny any other statement in this Request.

[51] http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm225223.htm.

REQUEST FOR ADMISSION NO. 107:

Pharmacia and Upjohn, a subsidiary of Pfizer, is an FDA-registered manufacturer of MPA.

RESPONSE TO REQUEST FOR ADMISSION NO. 107:

Denied as phrased.

REQUEST FOR ADMISSION NO. 108:

The FDA issued Warning Letters to Pfizer, or wholly owned subsidiaries, in July 2007, April 2008, April 2009, April 2010, August, 2011, May 2012, and June 2012.

RESPONSE TO REQUEST FOR ADMISSION NO. 108:

Plaintiffs object to this RFA in that it fails to sufficiently identify the "wholly owned subsidiaries" referenced in the RFA and therefore the Request is unduly burdensome and overly broad to the extent that it requires Plaintiffs to research every wholly owned subsidiary of Pfizer and review whether any such entity was issues a warning letter in the referenced time. After making a reasonable inquiry, Plaintiffs are without sufficient information to admit or deny the Request as posed.

REQUEST FOR ADMISSION NO. 110:

Compounding pharmacies compound medications for drug companies for use in clinical trials.[56] [57]

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[55] http://www.fda.gov/safety/recalls/enforcementreports/ucm234282.htm.

[56] FDA Compliance Policy Guidance on Pharmacy Compounding, CPG Sec. 460.200:

> In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:
>
> ...
>
> 3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.

RESPONSE TO REQUEST FOR ADMISSION NO. 110:

Plaintiffs object to this RFA because it is vague, ambiguous, and does not identify which compounding pharmacies and/or drug manufacturers that compound medications for use in clinical trials. Subject to and without waiving these objections, Plaintiffs state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[57] *E.g.*, http://www.restorehc.com/clinical-trials; http://www.mcguffpharmacy.com/ClinicalTrials/ClinicalTrialsHome.aspx.

REQUEST FOR ADMISSION NO. 113:

The report attached as Exhibit E is reliable.[1]

RESPONSE TO REQUEST FOR ADMISSION NO. 113:

Denied.

REQUEST FOR ADMISSION NO. 114:

Ninety-two percent (92%) of a representative sample of acute-care hospitals participating in Medicare used compounded sterile preparations in 2012.[58]

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[1] Exhibit E is the report from the OIG available online here: http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf. (This footnote was not in the original RFA. It has been added for clarification.)

[58] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 114:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 115:

Seventy-nine-point-four percent (79.4%) of a representative sample of acute-care hospitals participating in Medicare that used compounded sterile preparations outsourced the compounding to a supplier.[59]

[59] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 115:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 116:

Sixty-eight-point-one percent (68.1%) of a representative sample of acute-care hospitals participating in Medicare reported that shortages of commercial products were a very important factor when deciding whether to outsource compounded sterile preparations.[60]

[60] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 116:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 117:

Ninety-point-eight percent (90.8%) of a representative sample of acute-care hospitals participating in Medicare reported that shortages of commercial products was a very important or somewhat important factor when deciding whether to outsource compounded sterile preparations.[61]

[61] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 117:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 118:

Seventy-six-point-three percent (76.3%) of a representative sample of acute-care hospitals participating in Medicare reported that the need for special products was a very important or somewhat important factor when deciding whether to outsource compounded sterile preparations.[62]

[62] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 118:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 119:

Eighty-five-point-nine percent (85.9%) of a representative sample of acute-care hospitals participating in Medicare reported that product cost was a very important or somewhat important factor when selecting a particular outside pharmacy to compound sterile preparations.[63]

[63] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 119:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 120:

Following the fungal meningitis outbreak, of the hospitals in the representative sample of acute-care hospitals participating in Medicare that outsourced the compounding of compounded sterile preparations, 83% required compliance with USP 797, 71% reviewed quality reports provided by the outside pharmacy, 27% reviewed quality reports provided by a third party, 22%

conducted onsite visits at the outside pharmacy, and 9% tested the preparations provided by the outsource pharmacy.[64]

RESPONSE TO REQUEST FOR ADMISSION NO. 120:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 121:

Despite the survey taking place after the 2012 fungal meningitis outbreak, "few hospitals (11 of 236) in [the] sample reported problems with product contamination. . ."[65]

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[64] Exhibit E.
[65] Exhibit E.

RESPONSE TO REQUEST FOR ADMISSION NO. 121:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Plaintiffs further object to this Request as it is vague in that the term "after the 2012 fungal meningitis outbreak" is ambiguous. Plaintiffs further object to this Request as the term "the survey" is vague.

REQUEST FOR ADMISSION NO. 122:

"Half of all hospitals made changes or planned to make changes to CSP sourcing practices in response to the fall 2012 outbreak[.] Overall, 56% of hospitals made changes to CSP sourcing practices in 2012 or plan to make changes in 2013."[66]

RESPONSE TO REQUEST FOR ADMISSION NO. 122:

Plaintiffs object to this RFA as it is unlimited in time and Plaintiffs cannot admit or deny this RFA based on an unlimited timeframe. Plaintiffs further object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs to conduct a survey of a "representative sample of acute-care hospitals participating in Medicare." Plaintiffs further object because there is insufficient information available as to determine whether any survey was conducted with a sufficient sample to be considered a "representative sample" and Plaintiffs are not in possession of sufficient information to admit or deny. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

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[66] Exhibit E.

REQUEST FOR ADMISSION NO. 123:

The American Society of Health System Pharmacists ("ASHP") Research and Education Foundation's "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was not released until June 29, 2011.

RESPONSE TO REQUEST FOR ADMISSION NO. 123:

Plaintiffs admit that there is a version of a document entitled, "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" that bears a copyright date of 2011. With regard to when this document was released, Plaintiffs state Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 124:

The ASHP Research and Education Foundation developed the "ASHP Guidelines on Outsourcing Sterile Compounding Services" to assist health care organizations in choosing a compounding pharmacy when outsourcing the facility's existing in-house compounding services.

RESPONSE TO REQUEST FOR ADMISSION NO. 124:

Plaintiffs admit that the ASHP Foundation "strongly encourages hospitals/health systems to use this tool along with site visits to ensure a comprehensive review of potential sterile products outsourcing organizations. Items that should be closely evaluated during the site visit are indicated throughout the tool."

As to any other statement contained in RFA 124, Plaintiffs object to this RFA because it requires Plaintiffs to speculate as to why a document was or was not developed. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 125:

The ASHP Research and Education Foundation's "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was developed to assist pharmacy departments in choosing a compounding pharmacy when outsourcing the facility's existing in-house compounding services, but, by its terms, "it does not purport to establish a standard of care."

RESPONSE TO REQUEST FOR ADMISSION NO. 125:

Plaintiffs object to this RFA because it requires Plaintiffs to speculate as to why a document was or was not developed. Plaintiffs further state that Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

Further, to the extent that this RFA is meant to establish the "standard of care" applicable in any claim pending this MDL, Plaintiffs object because any such request would require Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g., Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

[67] http://www.ashp.org/DocLibrary/Midyear11/MCM11YellowPages.aspx.

REQUEST FOR ADMISSION NO. 127:

ASHP classified Ameridose and NECC as generic pharmaceutical exhibitors at the 46th ASHP Midyear Clinical Meeting & Exhibition.[68]

RESPONSE TO REQUEST FOR ADMISSION NO. 127:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[68] http://www.ashp.org/DocLibrary/Midyear11/MCM11YellowPages.aspx.
[69] http://www.ashp.org/DocLibrary/SM2011/Exhibitor-Yellow-Pages.aspx.

REQUEST FOR ADMISSION NO. 130:

Fungal contamination of MPA purchased from NECC was not reasonably foreseeable to the Defendants.

RESPONSE TO REQUEST FOR ADMISSION NO. 130:

Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 131:

Exhibit F and Exhibit G identify health care providers and facilities that purchased products from NECC as determined by the FDA in carrying out its authorized activities.

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[70] http://www.ashp.org/DocLibrary/SM2011/SM11-YellowPages-Web.aspx.

RESPONSE TO REQUEST FOR ADMISSION NO. 131:

Admitted that Exhibits F and G are a list of customers that purchased products from NECC as compiled by either the FDA or NECC. As to the remaining allegations, Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See e.g.*, *Iantosca v. Benistar Admin Servs., Inc.*, Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

REQUEST FOR ADMISSION NO. 132:

The health care providers and facilities identified in Exhibit G purchased the products from NECC in the amounts identified in Exhibit G.

RESPONSE TO REQUEST FOR ADMISSION NO. 132:

Admitted that Exhibit G identifies customers that purchased products from NECC as compiled by either the FDA or NECC.

REQUEST FOR ADMISSION NO. 133:

Exhibit H identifies health care providers and facilities that purchased MPA from NECC and received product from lots #05212012@68, #06292012@26, and #08102012@51 compounded by NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 133:

Admitted that Exhibit H identifies customers that purchased products from NECC as compiled by the CDC.

REQUEST FOR ADMISSION NO. 134:

Exhibits F, G, and H are records and data compilations of public agencies as contemplated by Fed. R. Evid. 803(8).

RESPONSE TO REQUEST FOR ADMISSION NO. 134:

Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 135:

The Plaintiffs' Steering Committee and/or individual Plaintiffs or counsel for individual Plaintiffs used or relied upon Exhibit F and/or Exhibit G to identify or allege that specific health care providers purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 135:

Plaintiffs object to this RFA to the extent that it seeks information not reasonably calculated to lead to the discovery of admissible evidence, is overly broad, unduly burdensome, and vague. Plaintiffs further object to the extent that this RFA seeks information that is covered by any applicable privilege.

REQUEST FOR ADMISSION NO. 136:

The Plaintiffs' Steering Committee and/or the individual Plaintiffs or counsel for the individual Plaintiffs used or relied upon Exhibit H to identify or allege that specific health care providers purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 136:

Plaintiffs object to this RFA to the extent that it seeks information not reasonably calculated to lead to the discovery of admissible evidence, is overly broad, unduly burdensome, and vague. Plaintiffs further object to the extent that this RFA seeks information that is covered by any applicable privilege.

REQUEST FOR ADMISSION NO. 137:

Between May 21, 2012, and October 6, 2012, more than 50 health care facilities/providers in Tennessee purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 137:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in Tennessee that purchased any medication from NECC. Subject to and without waiving this objection, after making a reasonable investigation, Plaintiffs are without sufficient information to admit or deny this request.

REQUEST FOR ADMISSION NO. 138:

Between May 21, 2012, and October 6, 2012, more than 180 health care facilities/providers in the United States purchased MPA from NECC.[71]

RESPONSE TO REQUEST FOR ADMISSION NO. 138:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 139:

Between May 21, 2012, and October 6, 2012, more than 90 health care facilities/providers in the United States purchased *preservative-free* MPA from NECC.[72]

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[71] Attached as Exhibit I is a summary of the information from Exhibit G, showing only the health care providers/facilities that purchased methylprednisolone acetate from NECC.

[72] Attached as Exhibit J is a summary of the information from Exhibit G, showing only the health care providers/facilities that purchased preservative-free methylprednisolone acetate from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 139:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any preservative free MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g., Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

REQUEST FOR ADMISSION NO. 140:

Between May 21, 2012, and October 6, 2012, more than 3,000 health care facilities/providers in the United States purchased medication from NECC.

RESPONSE TO REQUEST FOR ADMISSION NO. 140:

Plaintiffs object to this RFA as overly broad and unduly burdensome in that it requires Plaintiffs' Counsel to conduct a survey of facilities/providers in the entire country that purchased any MPA from NECC. Subject to and without waiving this objection, Plaintiffs' Counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' Counsel to

admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. *See e.g.*, *Henry v. Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities).

[73] *See* Exhibits F and G.

Dated: December 23, 2014

Respectfully submitted,

/s/ J. Gerard Stranch, IV

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